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**PATENTS**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Parsons, *et al.*

Serial No.: 10/721,031

Filed: November 24, 2003

For: STABLE COMPOSITIONS FOR  
MEASURING HUMAN NATRIURETIC  
PEPTIDES

Case No.: 7098.US.P1

Group Art No.: 1655

Examiner: Ralph J. Gitomer

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the:

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450 on:

 11/9/03  
Kim Annel Date

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Dear Sir:

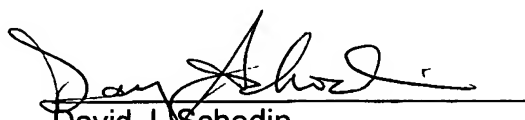
Enclosed herewith for the patent application identified above entitled STABLE COMPOSITIONS FOR MEASURING HUMAN NATRIURETIC PEPTIDES are the following:

1. Response to Restriction Requirement (3 Pages); and
2. Return Receipt Postcard

The Commissioner is hereby authorized to charge any additional Filing Fees required under 37 CFR §1.16, as well as any patent application processing fees under 37 CFR §1.17 associated with this communication for which full payment had not been tendered, to Deposit Account No. 01-0025.

Respectfully submitted,  
Parsons, *et al.*

ABBOTT LABORATORIES  
Customer Number 23492  
Telephone: (847) 936-3362  
Facsimile: (847) 938-2623

  
David J. Schodin  
Registration No. 41,294  
Attorney for Applicants



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PATENT

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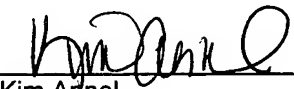
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Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450 on:

 11/19/04  
Kim Arnel Date

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

Dear Sir,

In response to the Office Action dated December 22, 2005, please consider the following remarks.

**RELATIONSHIP OF THE APPLICATIONS**

The Office Action inquires as to the relationship between the subject application, Application No. 10/620,475, and 11/248,650.

**Relationship to the '475 application**

The Office withdrew the '475 application from issue, without explanation, by way of a Petition under 37 CFR § 1.313. The decision on petition indicated that the reasons for withdrawal from issue would be communicated by the Examiner. Applicants have received neither the reasons for withdrawal, nor a copy of the petition upon which the Petitions Branch apparently acted. Applicants respectfully request a general indication of the reason(s) why the '475 application was withdrawn from issue.

This is applicants first filed case in this family.

**Relationship to the '650 application**

The subject patent application is a continuation of the '650 application. Having no indication of why the '475 application was withdrawn from issue, nor even a clear

indication that the '475 application would not be deemed abandoned for failure to file the issue fee, applicants filed the subject patent application out of an abundance of caution to preserve all rights in the subject application. Applicants intend to prosecute different aspects of the disclosed invention in the '475 and '650 applications.

#### The Subject Application

The subject application is a continuation-in-part to the '475 application. The subject patent application contains patent claims directed to stable test samples and methods of making the same for use in determining the quantity of natriuretic peptide contained in the sample, and so differs from the '650 and '475 application, which do not contain these claims.

#### RESPONSE TO RESTRICTION REQUIREMENT

The Office Action requires election of one of three identified inventions. Specifically, the Office Action requires election of one of Group I (claims 1-36), Group II (claims 37-51 and 83-94), and Group III (claims 95-106). Applicants note that claims 52—82 are not assigned to any particular Group although the Office Action indicates that these claims are pending.

Applicants provisionally elect Group III with traverse, because the Office requires election in any response. However, applicants respectfully inquire whether the Office Action contains a typographical error. Group II comprises both claims 37-51 and claims 83-94 and is said to be directed to a method of making a calibrator or control, however, claims 83-94 are directed to a method of making a stable test sample, which is different from a calibrator or control. A calibrator or control is used to establish a correlation between an immunoassay signal and the concentration of an analyte in the calibrator or is used to ensure that the instrument is performing within predefined specifications. In contrast, a test sample is obtained from a biological source (such as, e.g., a patient) and is made stable within the limitations of the claims directed thereto such that when the natriuretic peptide is determined, one can be less concerned about degradation of the natriuretic peptide than if one did not stabilize the reaction. Accordingly, the inventions set forth in the Office Action do not seem to correlate to the designated claims. Moreover, claims 52-82 do not seem to be assigned to any particular invention. Accordingly, as an alternative to withdrawing the Restriction Requirement in its entirety, applicants respectfully request a new Office Action.

A new Office Action would seem unnecessary, however, if the Office withdraws the requirement for restriction. A requirement for restriction is properly made only when (1) there are two or more patentably distinct inventions, and (2) the inventions cannot be simultaneously examined without undue burden on the Examiner. Applicants respectfully submit that the Restriction Requirement is not proper because it would not constitute an undue burden to search and consider each of the inventions. Each of the identified groups of claimed inventions is linked by the concept that stabilization of test samples, calibrators, and controls can be achieved, at least in part, by controlling the pH of the composition between about pH 4 and about pH 6 or pH 6.5. It is respectfully submitted that a complete patentability search for any one of the claimed inventions would seem to properly involve a search of references primarily pertaining to the other claimed invention because the Examiner might want to consider whether a reasonable suggestion of one of the claimed inventions could also reasonably be deemed to extend to the other claimed inventions. Accordingly, applicants respectfully request that each

of the identified inventions (defined by each of Groups I to III) as well as any undefined inventions (i.e., claims 52-82) be examined together.

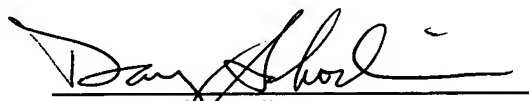
As yet another alternative, if the Office disagrees with the foregoing, applicants respectfully request that the Office withdraw the restriction requirement in part (i.e., make the restriction requirement two-way, rather than three-way).

### **Conclusion**

The application is considered in good form for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject patent application, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

ABBOTT LABORATORIES  
Customer Number 23492  
Telephone: (847) 936-3362  
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